K023656

DEC 3 0 2002

510(k) Summary of Safety and Effectiveness

510(k) Submitter: Streck Laboratories
7002 South 109th Street
La Vista, NE 68128

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402) 537-5313

Date Prepared: December 13, 2002

Names of Device:

Trade Name:	**Sickle-Chex Solubility Kit**
Common Name:	Sickle Cell Test
Classification Name:	Sickle Cell Test, 21CFR864.7825

Predicate Device: DADE Behring Inc., Dade® Sickle-Sol™Test.

Description:

Sickle-Chex Solubility Kit consists of:

A. Sickle-Chex Solubility Buffer; two LDPE bottles, each filled with 100mL of a 2.3M potassium phosphate buffer solution containing Saponin.
B. Sickle-Chex Reagent Powder; two glass vials, each filled with 4 grams of Sodium Hydrosulfite.

The testing principles of the kit is based on NCCLS, H10-A.

Intended Use:

Sickle-Chex Solubility Kit is a qualitative solubility test kit for testing the presence of sickling hemoglobins in human blood or sickle cell control material.

Comparison with Predicate Device:

Sickle-Chex Solubility Kit and Sickle-Sol™Test are similar and have the same intended application.

Sickle-Chex Solubility Kit adds the Saponin to the Phosphate buffer, where as Sickle-Sol Test adds to Saponin to the reagent powder.

Sickle-Chex Solubility Kit has 45 day open vial dating for the working solubility buffer, where as the Sickle-Sol Test has 30 day open vial dating for its working solubility solution.

Testing Performed:

In house studies were: Closed Vial Long Term studies on the Solubility Buffer and Reagent Powder, and Open Vial Studies on the working solubility solution. Off-site studies were conducted to verify the performance of Streck's Sickle-Chex Solubility Kit verses competitor(s) solubility kits.

Conclusions Drawn from the Tests:

Sickle-Chex Solubility Kit will perform satisfactorily as a qualitative solubility test kit for testing for the presence of sickling hemoglobins in human blood or sickle cell control material. Laboratories can be assured of correct results over the shelf life of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 3 0 2002

Ms. Kerrie Oetter
Quality Assurance Coordinator/
Regulatory Affairs
Streck Laboratories, Inc.®
7002 South 109th Street
LaVista, NE 68128

Re: k023656
Trade/Device Name: Sickle-Chex Solubility Kit
Regulation Number: 21 CFR 864.7825
Regulation Name: SickleTest System
Regulatory Class: Class II
Product Code: GHM
Dated: October 28, 2002
Received: October 30, 2002

Dear Ms. Oetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023656

Device Name: Sickle-Chex Solubility Kit

Indications For Use: Sickle-Chex Solubility Kit is a qualitative solubility test kit for testing the presence of sickling hemoglobins in human blood or sickle cell control material.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OD)

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Date: _____

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K023656